CLAIMS

What is claimed is:

1. A method for treating a person with a renal disease and/or renal complications of a disease, comprising:

(a) administering a treatment agent to a person in need thereof;

(b) obtaining a sample of body fluid from the person; and

(c) assaying for a protein in the sample, wherein either presence of or lack of presence of the protein in the urine or decreasing amount of the protein over time in the urine indicates that the treatment agent is therapeutically effective for the renal disease and/or renal complications of a disease.

2. The method according to claim 1, wherein the renal disease and/or renal complications of the disease is selected from the group consisting of nephropathy, diabetes insipidus, diabetes type I, diabetes II, renal disease (glomerulonephritis, bacterial and viral glomerulonephritides, IgA nephropathy and Henoch-Schönlein Purpura, membranoproliferative glomerulonephritis, membranous nephropathy, Sjögren's syndrome, nephrotic syndrome (minimal change disease, focal glomerulosclerosis and related disorders), acute renal failure, acute tubulointerstitial nephritis, pyelonephritis, GU tract inflammatory disease, Pre-clampsia, renal graft rejection, leprosy, reflux nephropathy, nephrolithiasis), genetic renal disease (medullary cystic, medullar sponge, polycystic kidney disease (autosomal dominant polycystic kidney disease, autosomal recessive polycystic kidney disease, tuborous sclerosis), von Hippel-Lindau disease, familial thin-glomerular basement membrane disease, collagen III glomerulopathy, fibronectin glomerulopathy, Alport's syndrome, Fabry's disease, Nail-Patella Syndrome, congenital urologic anomalies), monoclonal gammopathies (multiple myeloma, amyloidosis and related disorders), febrile illness (familial Mediterranean fever, HIV infection -AIDS), inflammatory disease (systemic vasculitides (polyarteritis nodosa, Wegener's granulomatosis, polyarteritis, necrotizing and crescentic glomerulonephritis), polymyositis-dermatomyositis, pancreatitis, rheumatoid arthritis, systemic lupus erythematosus, gout), blood disorders (sickle cell disease, thrombotic thrombocytopenia

purpura, hemolytic-uremic syndrome, acute corticol necrosis, renal thromboembolism), trauma and surgery (extensive injury, burns, abdominal and vascular surgery, induction of anesthesia), drugs (penicillamine, steroids) and drug abuse, malignant disease (epithelial (lung, breast), adenocarcinoma (renal), melanoma, lymphoreticular, multiple myeloma), circulatory disease (myocardial infarction, cardiac failure, peripheral vascular disease, hypertension, coronary heart disease, non-atherosclerotic cardiovascular disease, atherosclerotic cardiovascular disease), skin disease (psoriasis, systemic sclerosis), respiratory disease (COPD, obstructive sleep apnoea, hypoia at high altitude) and endocrine disease (acromegaly, diabetes mellitus, diabetes insipidus).

3. The method according to claim 1, wherein the treatment agent is a lysosome-activating compound.

4. The method according to claim 3, wherein the lysosome-activating compound is selected from the group consisting of ACE inhibitors, anti-glycation agents, anticancer compounds, antiproliferation compounds, and compounds that neutralize TGF-beta.

5. The method according to claim 3, wherein the lysosome-activating compound is selected from the group consisting of ramipril, aminoguanidine, paracetamol, vitamin A (retinoic acid), retinol derivatives, and anti-TGF beta antibodies.

6. The method according to claim 1, wherein the sample of body fluid is a urine, blood or laboratory sample.

7. The method according to claim 1, wherein the protein comprises albumin, globulin (α-globulin(α_1-globulin, α_2-globulin),β -globulin,γ -globulin), euglobulin, pseudoglobulin I and II, fibrinogen, α_1 acid glycoprotein (orosomucoid), α_1 glycoprotein, α_1 lipoprotein, ceruloplasmin, α_2 19S glycoprotein, β_1 transferrin, β_1 lipoprotein, immunoglobulins A, E, G, and M, horseradish peroxidase, lactate dehydrogenase, glucose oxidase, myoglobin, lysozyme, protein hormone, growth hormone, insulin, or parathyroid hormone.

8. The method according to claim 1, wherein the assaying for a protein in the sample comprises a method selected from the group consisting of:

(a) assaying for albumin by a conventional method; and

(b) assaying for intact modified albumin.

9. The method according to claim 8, wherein the conventional method comprises a method selected from the group consisting of:

(a) an antibody method, and

(b) a non-antibody method comprising loading the sample on a chromatography, electrophoresis or sedimentation apparatus to test for native or intact modified albumin.

10. The method according to claim 9, wherein the albumin is detected by an antibody that is specific for both unmodified and modified forms of the protein.

11. The method according to claim 9, wherein the albumin is detected by an antibody that is specific for the modified protein.

12. The method according to claim 9, wherein the albumin is detected by an antibody that is attached to an enzymatic, radioactive, fluorescent or chemiluminescent label, wherein the detecting step comprises radioimmunoassay, immunoradiometric assay, fluorescent immunoassay, enzyme linked immunoassay, or protein A immunoassay.

13. The method according to claim 1, wherein the assaying for a protein in the sample comprises the steps of:

(i) detecting native albumin amount by conventional antibody assay:

(ii) detecting intact modified albumin by a non-antibody method; and

(iii) adding the values obtained in (i) and (ii) to obtain an accurate reading of total albumin content in the sample.

14. The method according to claim 13, wherein the non-antibody method comprises loading the sample on a chromatography, electrophoresis or sedimentation apparatus to test for native or intact modified albumin.

15. The method according to claim 1, wherein the assaying for a protein in the sample is a non-antibody method comprising detecting a sum of native protein and intact modified protein in a sample.

16. The method according to claim 1, wherein the assaying for a protein in the sample is by a method selected from the group consisting of partition chromatography, adsorption chromatography, paper chromatography, thin-layer chromatography, gas-liquid chromatography, gel chromatography, ion-exchange chromatography, affinity chromatography, or hydrophobic interaction chromatography, moving-boundary electrophoresis, zone electrophoresis, or isoelectric focusing.

17. The method according to claim 1, wherein the assaying for a protein in the sample is by hydrophobic interaction chromatography carried out in a high pressure liquid chromatography (HPLC) apparatus.

18. The method according to claim 1, wherein the assaying for a protein in the sample is by detecting albumin in the sample with specific albumin dyes.

19. The method according to claim 1, wherein an early stage of the disease is diagnosed when modified albumin is present in the sample in increasing amounts over time.

~~20.~~ ~~A method for identifying a treatment agent for renal disease and/or renal complications of a disease, comprising:~~

~~(a) administering to a person in need thereof an agent that is suspected of being able to treat the disease;~~

~~(b) obtaining a urine sample from the person; and~~

~~(c) assaying for a protein in the sample, wherein either presence of or lack of presence of the protein in the urine or decreasing amount of the protein over time in the urine indicates that the agent is a treatment agent for the renal disease and/or renal complications of a disease.~~

Sub. a6

21. The method of claim ~~19~~, wherein the for a protein in the sample comprises assaying for a modified form of albumin in the sample, wherein either presence of or a lack of presence of the modified form of the protein in the sample or decreasing amount of the modified form of the protein over time in the urine indicates that the agent is a treatment agent for the ~~renal disease and/or renal complications of a disease.~~

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